

**REMARKS****Petition To Revive**

In a telephone call to applicant's counsel, the Examiner indicated that a response to an Office Action (Paper No. 19) had not been filed. In checking the file for the above application, applicant's counsel found that the Office Action had not been received. Applicant respectfully petitions to revive the application. Please charge all fees with respect thereto to the deposit account indicated on the Transmittal.

**Response to Continued Examination Under 37 C.F.R. §1.114**

The Examiner put forth a requirement for the identification of the species that is elected and a listing of all claims readable thereon. The applicant previously elected the claims 1-9, 29, 30 and 35-44. Applicant elects the species shown in Figure 1 and note that pending claims 1 and 29 read on the elected species.

**Response to Double Patenting**

Claims 1-4, 6-8, and 11 are rejected by the Examiner under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 and 5-10 of U.S. Patent No. 6,468,300 alone. In response applicants have filed concurrently herewith a Terminal Disclaimer (By Attorney) which should overcome the rejection.

**Response to Claim Rejections Under 35 U.S.C. §112**

Claims 1, 9, 11, 29, 30, 35-38 and 41-46 are rejected by the Examiner under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The

Examiner contends that the range "less than 0.45 mm" lacks clear antecedent basis from the specification and because it is essential subject matter it must have "clear explicit support from the specification".

Applicants object to the rejection on the basis that 35 U.S.C. §112 does not require a "clear antecedent basis" as used by the Examiner and does not require "clear explicit support" as contended by the Examiner. Moreover, the Examiner has cited no case law which requires a "clear antecedent basis" or which requires "clear explicit support from the specification" to satisfy 35 U.S.C. §112. The Examiner seems to be requiring an *in haec verba* description to meet the §112 requirements. However, such requirements have been struck down in many court decisions interpreting §112. See for example, Chisum §7.04[1][e], see pages 7-187 to 7-196 (copy attached).

However, notwithstanding the improper basis for the Examiner's rejection, applicants wish to point out that there is substantial support in applicant's specification for the range of "less than 0.45 mm". Reference is made to a thickness of less than 0.75 mm and preferred ranges of 0.05-0.20 mm and an average thickness of 0.45 mm. All of this would support the expression "less than 0.45 mm". Additionally, the present application incorporates by reference co-pending application Serial No. 08/935,784, which issued as U.S. Patent No. 6,468,300. In column 2, line 67 to column 3, line 2, reference is made to a thickness of "0.45 mm or less" as being preferred. Based on the above, applicant respectfully submits that there is more than adequate support for the claimed range and respectfully request that this rejection be withdrawn.

**Response to Claim Rejections Under 35 U.S.C. §103**

Claims 2, 9, 37, and 43-45 are rejected by the Examiner under 35 U.S.C. §103(a) as being unpatentable over Winston et al. (U.S. Pat. No. 6,117,166) alone where the effective filing date of these claims is September 17, 1998.

Applicant notes that the rejected claims are dependent claims and the Winston et al. reference was not used to reject the independent claims from which these claims depend, nor would the independent claims from which these dependent claims would depend be unpatentable over the Winston et al. reference. If the independent claims from which these dependent claims depend are not rejected on and are indeed patentable over Winston et al., these dependent claims must therefore be patentable over Winston et al. reference. If the independent claim is patentable over Winston et al., then the claims which depend from these independent claims must necessarily be patentable over the Winston et al. reference.

Claims 29, 30, 36-38 and 41-44 were rejected by the Examiner under 35 U.S.C. 103(a) as being unpatentable over Love (WO 97/24081) in view of Winston et al. (U.S. Pat. No. 6,117,166). The Examiner contends that Love meets the claim language completely except for the thinned state of the tissue. Applicant believes that the Examiner is in error in this regard, particularly with the clarifying amendments made to claim 29. Specifically, the tissue (12) and the supporting frame forming the prosthesis of Love are not configured to be expanded to the final in situ size as required by the rejected claims. Furthermore, the combination of references cited by the Examiner does not does not teach a cylindrical jacket which encircles the outer surface of the stent in a wrapped configuration and which is configured to unwrap as the stent

expands. This feature found in the original and amended claims is not suggested in either of these references. Winston also does not teach a jacket which encircles the stent. The applicant submits that the Examiner's rejection appears flawed in several instances and should be withdrawn.

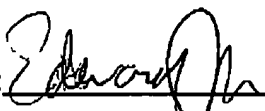
Claims 1-4, 6-9, 11, 29, 30, 36-38, and 41-42 are rejected by the Examiner under 35 U.S.C. 103(a) as being unpatentable over Love (WO 97/24081) in view of Love et al. (U.S. Pat. No. 5,163,955). In this rejection the Examiner contends that Love et al., (U.S.) teaches that pericardial tissue varies from about 15 to 20 mils. However, Love et al. (U.S.) is directed to autologous tissue which is described as having a thickness of about 10-12 mils (0.25-0.31 mm), the 15-20 mils refers to bovine pericardium. While some bovine pericardium may have a thickness within the range of 15-20 mils, the statement is not relevant to thinned heterologous tissue less than 0.45 mm as called for in the claims. Moreover, there would be no suggestion to combine the references as suggested by the Examiner to arrive at the presently claimed invention. Both Love references are directed to prostheses which replace a blood vessel or valve, whereas, the present application is directed to a stent assembly which supports the lumen of an existing vessel, not to replace it, i.e. it is not a prosthesis.

Claim 5 is rejected by the Examiner under 35 U.S.C. 103(a) as being unpatentable over Winston et al. (U.S. Pat. No. 6,117,166) in view of Narciso (WO 94/15583). However, as discussed above, the Examiner has not rejected claim 1 over the Winston et al. reference. That being the case, claim 5 which depends from claim 1 is at least patentable over the Winston et al. patent and Narciso fails to teach any deficiencies which the Winston et al reference has with respect to teaching the presently

Claim 35 is rejected by the Examiner under 35 U.S.C. 103(a) as being unpatentable over Love (WO 97/24081) and Love et al. (U.S. Pat. No. 5,163,955) as set forth in the previous rejection and in further view of Dereume (U.S. Pat. No. 5,653,747). However, neither Love nor Love et al. meet the requirements of claim 1 as discussed above and Dereume would not make up for the deficiencies of Love or Love et al.

Applicants submit that the pending claims are directed to patentable subject matter. Reconsideration and an early allowance of the pending claims are earnestly solicited.

Respectfully submitted,

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VOLUME 3

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## ADEQUATE DISCLOSURE

§ 7.04[1][e]

It is properly employed as a basis for objection to amendments to the abstract, specifications, or drawings attempting to add new disclosure to that originally presented.”<sup>39</sup>

**[e]—Adequate Description Standard: Clear Conveyance—Absence of “In Haec Verba” Description—Obviousness—Inherency.** The subject matter of the later claim need not be described literally or “in haec verba” in order for the specification to satisfy the description requirement.<sup>40</sup> It is sufficient that the

<sup>39</sup> 650 F.2d at 1214-15, 211 USPQ at 326.

See also *Waldemar Link, GmbH & Co. v. Osteonics Corp.*, 32 F.3d 556, 559, 31 USPQ2d 1855, 1857 (Fed. Cir. 1994) (“If an Examiner determines that an amended claim recites elements without support in the parent disclosure, the proper basis of rejection is 35 U.S.C. § 112, first paragraph.”); *Texas Instruments Inc. v. U.S. Int’l Trade Comm’n*, 871 F.2d 1054, 10 USPQ2d 1257 (Fed. Cir. 1989).

<sup>40</sup> *In re Lukach*, 442 F.2d 967, 969, 169 USPQ 795 (CCPA 1971).

Accord: *Martin v. Johnson*, 454 F.2d 746, 751, 172 USPQ 391, 395 (CCPA 1972) (“the description need not be in *ipsis verbis* to be sufficient”).

See also *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1323, 56 USPQ2d 1481, 1483 (Fed. Cir. 2000) (“In order to satisfy the written description requirement, the disclosure as originally filed does not have to provide *in haec verba* support for the claimed subject matter at issue.”); *Lampi Corp. v. American Power Products, Inc.*, 228 F.3d 1365, 1378, 56 USPQ2d 1445, 1455 (Fed. Cir. 2000) (“In order to satisfy the written description requirement, the disclosure as originally filed need not provide *in haec verba* support for the claimed subject matter at issue.”); *Union Oil Co. of California v. Atlantic Richfield Co.*, 208 F.3d 989, 997, 54 USPQ2d 1227, 1232 (Fed. Cir. 2000), *cert. denied*, 121 S. Ct. 1167 (2001) (“The written description requirement does not require the applicant ‘to describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.’”; “The written description requirement does not require identical descriptions of claimed compounds, but it requires enough disclosure in the patent to show one of skill in this art that the inventor ‘invented what is claimed.’”; *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1570, 39 USPQ2d 1895, 1904 (Fed. Cir. 1996) (“*ipsis verbis* disclosure is not necessary to satisfy the written description requirement of section 112. Instead, the disclosure need only reasonably convey to persons skilled in the art that the inventor had possession of the subject matter in question.”); *In re Alton*, 76 F.3d 1168, 1175, 37 USPQ2d 1578, 1584 (Fed. Cir. 1996) (“If a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate written description requirement is met.”); *In re Herschler*, 591 F.2d 693, 200 USPQ 711 (CCPA 1979); *Flynn v. Eardley*, 479 F.2d 1393, 1395, 178 USPQ 288, 289 (CCPA 1973) (“It is not essential to *name* the claimed compounds, and further . . . *preference* for the specific claimed compounds is not necessarily a requirement.”); *Fields v. Conover*, 443 F.2d 1386, 1391, 170 USPQ 276 (CCPA 1971); *ADCO Products, Inc. v. Carlisle Syntec Inc.*, 110 F. Supp.2d 276, 291 (D. Del. 2000) (“To satisfy the written description requirement, the patent specification must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, the applicant was in possession of the claimed invention. . . . It is not necessary for an applicant to describe exactly the subject matter claimed, so long as the written description allows persons of ordinary skill in the art to recognize that the applicant invented what is claimed.”); *Novo Nordisk A/S v. Becton Dickinson & Co.*, 96 F. Supp.2d 309, 314 (S.D. N.Y. 2000) (“§ 112 does not require

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specification "convey clearly to those skilled in the art, to whom it is addressed, in any way, the information that the applicant has invented the specific subject matter later claimed."<sup>41</sup>

the express recitation in the parent application of every feature of the claims in a later continuation-in-part application, but rather calls for a determination on a case-by-case basis of whether a person of ordinary skill in the art would consider the later claimed subject matter to be part of the invention as originally disclosed"; INHERENT PART: "In reaching that determination, material which is inherently part of the disclosure, even though not expressly disclosed, must be considered."); *Monsanto Co. v. Mycogen Plant Science, Inc.*, 61 F. Supp. 2d 133, 188 (D. Del. 1999), *later appeal*, 261 F.3d 1356, 59 USPQ2d 1980 (Fed. Cir. 2001) ("The applicant need not describe the subject matter claimed in exact terms."); *Emory University v. Glaxo Wellcome Inc.*, 44 USPQ2d 1407, 1412 (N.D. Ga. 1997) ("To meet the requirement of Section 112, the patent application need not utilize any particular form of disclosure."); *Sun Products Group Inc. v. B & E Sales Co. Inc.*, 700 F. Supp. 366, 9 USPQ2d 2009 (E.D. Mich. 1988); *Nelson v. Bowler*, 1 USPQ2d 2076, 2078 (Bd. Pat. App. & Int'f 1986) ("It is not necessary that the claimed subject matter be described in *ipsis verbis* to satisfy the written description requirement of 35 USC 112.").

See generally *Duft & Mirabel*, "Principles of Inherency," 77 J. Pat. & Trademark Off. Soc'y 539 (1995).

<sup>41</sup> *In re Wertheim*, 541 F.2d 257, 262, 191 USPQ 90, 97 (CCPA 1976), *appeal after remand*, 646 F.2d 527, 209 USPQ 554 (CCPA 1981).

See also *Lampi Corp. v. American Power Products, Inc.*, 228 F.3d 1365, 56 USPQ2d 1445 (Fed. Cir. 2000); *Union Oil Co. of California v. Atlantic Richfield Co.*, 208 F.3d 989, 997, 54 USPQ2d 1227, 1232 (Fed. Cir. 2000), *cert. denied*, 121 S. Ct. 1167 (2001) ("§ 112, ¶ 1 ensures that, as of the filing date, the inventor conveyed with reasonable clarity to those of skill in the art that he was in possession of the subject matter of the claims."); *In re Daniels*, 144 F.3d 1452, 1456, 46 USPQ2d 1788, 1790 (Fed. Cir. 1998), discussed at § 1.04[3] ("The test for sufficiency of the written description is the same, whether for a design or a utility patent. This test has been expressed in various ways; for example, 'whether the disclosure of the application relied upon 'reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter.' " *Ralston Purina Co. v. Far-Mar-Co, Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting *In re Kaslow*, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983)). When the earlier disclosure is less than clear on its face, courts have explained that the prior application must 'necessarily' have described the later claimed subject matter. *Kennecott Corp. v. Kyocera Int'l, Inc.*, 835 F.2d 1419, 1423, 5 USPQ2d 1194, 1198 (Fed. Cir. 1987). In general, precedent establishes that although the applicant 'does not have to describe exactly the subject matter claimed, the description must clearly allow persons of ordinary skill in the art to recognize that [the applicant] invented what is claimed.' *In re Gosteli*, 872 F.2d at 1012, 10 USPQ2d at 1618 (citations omitted)."); *In re Mayhew*, 481 F.2d 1373, 1376, 179 USPQ 42 (CCPA 1973), *appeal after remand*, 527 F.2d 1229, 188 USPQ 356, (CCPA 1976); *In re Smythe*, 480 F.2d 1376, 1382, 178 USPQ 279 (CCPA 1973); *Flynn v. Eardley*, 479 F.2d 1393, 1395, 178 USPQ 288 (CCPA 1973); *Smith v. Horne*, 450 F.2d 1401, 171 USPQ 755 (CCPA 1971); *In re Ruschig*, 379 F.2d 990, 996, 154 USPQ 118, 123 (CCPA 1967) ("Does the specification convey clearly to those skilled in the art, to whom it is addressed, in any way, the information that appellants invented that specific compound?"); *Standard Oil Co. v. Montedison, S.p.A.*, 664 F.2d 356, 368, 212 USPQ 327, 337-8 (3d Cir. 1981), *cert. denied*, 456 U.S. 915 (1982) ("adequate disclosure may be by any means, since the objective is to communicate the invention to the reader who is skilled in the art"); *Plastic Container Corp. v. Continental Plastics of Oklahoma, Inc.*, 607 F.2d 885, 886, 203 USPQ 27, 36 (10th Cir. 1979), *cert. denied*, 444 U.S. 1018 (1980), *on remand*, 515 F. Supp. 834, 214 USPQ

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In *Kennecott Corp. v. Kyocera International, Inc.* (1987),<sup>42</sup> the Federal Circuit noted: "[T]he earlier and later applications need not use the identical words, if the earlier application shows the subject matter that is claimed in the later application, with adequate direction as to how to obtain it . . . [A]n invention may be described in different ways and still be the same invention."<sup>43</sup> In *Vas-Cath Inc. v. Mahurkar* (1991),<sup>44</sup> it noted:

"Since its inception, the Court of Appeals for the Federal Circuit has frequently addressed the 'written description' requirement of § 112 . . . . A fairly uniform standard for determining compliance with the 'written description' requirement has been maintained throughout: 'Although [the applicant] does not have to describe exactly the subject matter claimed, . . . the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.' *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (citations omitted). '[T]he test for sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter."' *Ralston Purina Co. v. Far-Mar-Co.*, 772 F.2d 1570, 1575, 227 USPQ 117, 179 (Fed. Cir. 1985) (quoting *In re Kaslow*, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983). Our cases also provide that compliance with the 'written

530 (W.D. Okla. 1980), *aff'd in part & rev'd in part*, 708 F.2d 1554, 219 USPQ 26 (10th Cir. 1983) ("To satisfy the description requirement of this section of the statute, an application must contain sufficient disclosure, expressly or inherently, to make it clear to one skilled in the art that the patentee was in possession of the claimed subject matter at the time of the filing of the application.").

Cf. *Atmel Corp. v. Information Storage Devices, Inc.*, 198 F.3d 1374, 1379-80, 53 USPQ2d 1225, 1228 (Fed. Cir. 1999), discussed at § 8.04[2][d] (definiteness of claim containing a "means-plus-function" clause depends on whether the specification adequately disclosed structure performing the function; the adequacy of a specification's disclosure of corresponding structure should be evaluated by reference to the understanding of persons skilled in the pertinent art; "the 'one skilled in the art' analysis in this context is in accord with [a] related analysis under § 112, ¶ 1, . . . viz, . . . written description, see *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991) (holding that, to satisfy the written description requirement, 'the applicant must . . . convey with reasonable clarity to those skilled in the art that . . . he or she was in possession of the invention.')).

<sup>42</sup> *Kennecott Corp. v. Kyocera International, Inc.*, 835 F.2d 1419, 1422, 5 USPQ2d 1194, 1197 (Fed. Cir. 1987), *cert. denied*, 486 U.S. 1008 (1988), discussed at § 13.04[4][b].

See also *Therma-Tru Corp. v. Peachtree Doors Inc.*, 44 F.3d 988, 33 USPQ2d 1274 (Fed. Cir. 1995).

<sup>43</sup> 835 F.2d at 1422, 5 USPQ2d at 1197.

Compare *Applied Materials Inc. v. Advanced Semiconductor Materials America, Inc.*, 98 F.3d 1563, 40 USPQ2d 1481 (Fed. Cir. 1996), discussed at § 13.04[4][a].

<sup>44</sup> 935 F.2d 1555, 19 USPQ2d 1111 (Fed. Cir. 1991), discussed at § 7.04[4].

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description' requirement of § 112 is a question of fact, to be reviewed under the clearly erroneous standard."<sup>45</sup>

<sup>45</sup> 935 F.2d at 1563-63, 19 USPQ2d at 1116 (Fed. Cir. 1991), discussed at § 7.04[4].

See also *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1323, 56 USPQ2d 1481, 1483 (Fed. Cir. 2000) (IMMEDIATELY DISCERN: "the disclosure must . . . convey with reasonable clarity to those skilled in the art that . . . [the inventor] was in possession of the invention. *Vas-Cath* . . . Put another way, one skilled in the art, reading the original disclosure, must immediately discern the limitation at issue in the claims. *Waldemar Link GmbH & Co. v. Osteonics Corp.*, 32 F.3d 556, 558, 31 USPQ2d 1855, 1857 (Fed. Cir. 1994). That inquiry is a factual one and must be assessed on a case-by-case basis."); *Hyatt v. Boone*, 146 F.3d 1348, 47 USPQ2d 1128 (Fed. Cir. 1998), *cert. denied*, 525 U.S. 1141 (1999), discussed at § 13.04[4][a]; *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 USPQ2d 1498, 1502-03 (Fed. Cir. 1998), discussed at § 7.04[2] ("To fulfill the written description requirement, the patent specification 'must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.' *In re Gosteli* . . . (Fed. Cir. 1989). An applicant complies with the written description requirement 'by describing the invention, with all its claimed limitations.' *Lockwood v. American Airlines, Inc.* . . . (Fed. Cir. 1997)."); *Regents of University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1566, 43 USPQ2d 1398, 1404 (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1089 (1998) ("To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that 'the inventor invented the claimed invention.' *Lockwood v. American Airlines, Inc.* . . . (Fed. Cir. 1997); *In re Gosteli* . . . (Fed. Cir. 1989) ('[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.'). Thus, an applicant complies with the written description requirement 'by describing the invention, with all its claimed limitations, not that which makes it obvious,' and by using 'such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention.' *Lockwood* . . ."); *Eiselstein v. Frank*, 52 F.3d 1035, 1038-39, 34 USPQ2d 1467, 1470 (Fed. Cir. 1995) ("In order to determine whether a prior application meets the 'written description' requirement with respect to later-filed claims, the prior application need not describe the claimed subject matter in exactly the same terms as used in the claims; it must simply indicate to persons skilled in the art that as of the earlier date the applicant had invented what is now claimed . . . . The test is whether the disclosure of the application relied upon reasonably conveys to a person skilled in the art that the inventor had possession of the claimed subject matter at the time of the earlier filing date . . . . 'Precisely how close the original description must come to comply with the description requirement of § 112 must be determined on a case-by-case basis.' "); *Waldemar Link, GmbH & Co. v. Osteonics Corp.*, 32 F.3d 556, 558-59, 31 USPQ2d 1855, 1857 (Fed. Cir. 1994) ("The fact finder must determine if one skilled in the art, reading the original specification, would immediately discern the limitation at issue in the patent. . . . In other words, does the 'disclosure of the application relied upon reasonably convey[] to the artisan that the inventor had possession at that time of the later claimed subject matter'? . . . Furthermore, before making any factual determination about the disclosure of newly added material, the trial court examines the circumstances surrounding the prosecution of the patent application."); *Mendenhall v. Cedarapids, Inc.*, 5 F.3d 1557, 28 USPQ2d 1081 (Fed. Cir. 1993), *cert. denied*, 511 U.S. 1031 (1994), discussed at § 13.04[4][a]; *Jewish Hospital of St. Louis v. IDEXX Laboratories*, 951 F. Supp. 2, 5, 42 USPQ2d 1720, 1723 (D. Maine 1996), discussed at § 13.04[4] ("Since the continuation-in-part provides inherent characteristics of the items previously disclosed in the 1983 application, it does not result in a later effective date."); *Hoechst Celanese Corp. v. BP Chemicals Ltd.*, 844 F. Supp. 336, 340, 30 USPQ2d 1833, 1836 (S.D. Tex. 1994), *aff'd in part, vacated in part*, 65 F.3d 188 (Fed. Cir. 1995) (unpublished) ("the test for the written description is not whether a skilled artisan would have known that lithium iodide was

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In *In re Hayes Microcomputer Products Inc. Patent Litigation* (1992),<sup>46</sup> the Federal Circuit disparaged an argument that a patent violated the Section 112 description requirement because "the heart of the claimed invention . . . is described only in twenty-seven lines": "Certainly no length requirement exists for a disclosure to adequately describe an invention. While some inventions require more disclosure, the adequacy of the description of an invention depends on its content in relation to the particular invention, not its length."<sup>47</sup>

In *Lockwood v. American Airlines, Inc.* (1997),<sup>48</sup> the Federal Circuit cautioned that written description requirement compliance must focus on what the

'suitable' in similar processes; the test is whether the artisan would have known, from reading the description, that the inventor . . . did know of this suitability—and hence had possession of this invention."); *Therma-Tru Corp. v. Peachtree Doors Inc.*, 24 USPQ2d 1493, 1497 (E.D. Mich. 1992), *affirmed in part, rev'd in part*, 44 F.3d 988, 33 USPQ2d 1274 (Fed. Cir. 1995) (jury instruction: "The filing date of the patent is the first date an application was filed that reasonably conveys to those in the art that [the applicant] had possession of all of the subject matter of [the] claims . . ."); *May v. Carriage Inc.*, 688 F. Supp. 408, 416, 7 USPQ2d 1593, 1600 (N.D. Ind. 1988) ("The test is whether the specification would have reasonably conveyed to one of ordinary skill that the inventor invented the later-claimed subject matter."); *Rohm & Haas Co. v. Mobil Oil Corp.*, 212 USPQ 354 (D. Del. 1981) (citing *Treatise*); *Ex parte Rodgers*, 27 USPQ2d 1738, 1743 n.11 (Bd. Pat. App. & Int'l 1992) ("It is not necessary that the claimed subject matter be described identically, but the disclosure originally filed must convey to those skilled in the art that the applicant had invented the subject matter later claimed."); *Behr v. Talbott*, 27 USPQ2d 1401, 1407 (Bd. Pat. App. & Int'l 1992) ("It is not necessary for the applicant to reveal a conscious appreciation on the part of the applicants of the significance of the limitation in question. . . . The written description requirement can be satisfied by showing that the disclosed subject matter, when given its 'necessary and only reasonable construction,' inherently (i.e., necessarily) satisfies the limitation in question."); *Staehelin v. Secher*, 24 USPQ2d 1513, 1520 (Bd. Pat. App. & Int'l 1992) (a specification need not "describe the exact details for preparing every species within the genus described"); *Ex parte Rohrer*, 20 USPQ2d 1460 (Bd. Pat. App. & Int'l 1991); *Ex parte Holt*, 19 USPQ2d 1211, 1213 (Bd. Pat. App. & Int'l 1991); *Ex parte Remark*, 15 USPQ2d 1498, 1506 (Bd. Pat. App. & Int'l 1990) ("The test for determining compliance with the written description requirement is whether the disclosure of an application as originally filed reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter.").

See generally Killworth, "The Federal Circuit Treatment of Non-Art Rejections/Defenses and Reissue/Reexamination: The First Three Years," 13 AIPLA Q.J. 220, 223-24 (1985); Rollins, "What's New (Matter, That Is)," 66 J. Pat. Off. Soc'y 514 (1984).

<sup>46</sup> *In re Hayes Microcomputer Products Inc. Patent Litigation*, 982 F.2d 1527, 25 USPQ2d 1241 (Fed. Cir. 1992), discussed at § 7.05[1]; § 8.04[2][d].

<sup>47</sup> 982 F.2d at 1534, 25 USPQ2d at 1246.

<sup>48</sup> *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 41 USPQ2d 1961 (Fed. Cir. 1997).

See also *Tronzo v. Blomet Inc.*, 156 F.3d 1154, 1158, 47 USPQ2d 1829, 1832 (Fed. Cir. 1998), discussed at § 6.02[9] and § 7.04[2] ("For a claim in a later-filed application to be entitled to the filing date of an earlier application under 35 U.S.C. § 120 (1994), the earlier application must comply with the written description requirement of 35 U.S.C. § 112, . . . (1994). . . . To meet this requirement, the disclosure of the earlier application, the parent, must reasonably convey to one of skill in the art that the inventor possessed the later-claimed subject matter at the time the

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specification discloses and not on what would have been obvious to a person skilled in the art from the disclosure.

"It is the disclosures of the applications that count. Entitlement to a filing date does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed. It extends only to that which is disclosed. While the meaning of terms, phrases, or diagrams in a disclosure is to be explained or interpreted from the vantage point of one skilled in the art, all the limitations must appear in the specification. The question is not whether a claimed invention is an obvious variant of that which is disclosed in the specification. Rather, a prior application itself must describe an invention, and do so in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention as of the filing date sought. *See Martin v. Mayer*, 823 F.2d 500, 504, 3 USPQ2d 1333, 1337 (Fed. Cir. 1987) (stating that it is 'not a question of whether one skilled in the art *might* be able to construct the patentee's device from the teachings of the disclosure. . . . Rather, it is a question whether the application necessarily discloses that particular device.') (quoting *Jepson v. Coleman*, . . . 314 F.2d 533, 536, 136 USPQ 647, 649-50 (1963)). [The patentee] argues that all that is necessary to satisfy the description requirement is to show that one is 'in possession' of the invention. [The patentee] accurately states the test, *see Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), but fails to state how it is satisfied. One shows that one is 'in possession' of the invention by describing the invention, with all its claimed limitations, not that which makes it obvious. *Id.* ('[T]he applicant must also convey to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the "written description" inquiry, whatever is now claimed.') (emphasis in original). One does that by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention. Although the exact terms need not be used in *haec verba*, *see Eiselstein v. Frank*, 52 F.3d 1035,

parent application was filed. . . . A disclosure in a parent application that merely renders the later-claimed invention obvious is not sufficient to meet the written description requirement; the disclosure must describe the claimed invention with all its limitations."); *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 45 USPQ2d 1498 (Fed. Cir. 1998), discussed at § 7.04[2] (claims broadened after application filed invalid for want of written description even though they were patentable over the prior art); *Regents of University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1567, 43 USPQ2d 1398, 1405 (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1089 (1998), discussed at § 7.04[2] (in *Lockwood*, "we held that a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement of that invention"); *ADCO Products, Inc. v. Carlisle Syntec Inc.*, 110 F. Supp.2d 276, 292 (D. Del. 2000) (SIMILAR OR INTERCHANGEABLE? "The court finds no authority for interpreting this provision as requiring only that the applicant must provide a written description of structures 'similar to' or 'interchangeable with' the claimed invention.").

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1038, 34 USPQ2d 1467, 1470 (Fed. Cir. 1995) ('[T]he prior application need not describe the claimed subject matter in exactly the same terms as used in the claims . . .'), the specification must contain an equivalent description of the claimed subject matter. A description which renders obvious the invention for which an earlier filing date is sought is not sufficient."<sup>49</sup>

In *Lockwood*, the court held that a declaration by the patentee's expert did not raise a genuine issue of material fact precluding summary judgment of noncompliance with the written description requirement because the declaration was only directed to what a person skilled in the art could have done with what was disclosed: "It is not sufficient for purposes of the written description requirement of § 112 that the disclosure, when combined with the knowledge in the art, would lead one to speculate as to modifications that the inventor might have envisioned, but failed to disclose."<sup>50</sup>

A structure or process not explicitly described may meet the clear conveyance standard if it is "inherent" in what is described. In *Standard Oil Co. v. Montedison, S.p.A.* (1980),<sup>51</sup> the infamous polypropylene interference case, Judge Caleb Wright noted that "patent entitlement is based on scientific skill and diligence and not on the ability to manipulate English synonyms. . . . Legal equivalence, or inherency, may be established either by the direct meaning of the language or by inferences drawn from the terms of the initial disclosure. Legal equivalence may also be proven by the use of circumstantial evidence showing successful experiments reproducing the initial application."<sup>52</sup> Judge Wright rejected the argument that a product must be "invariably" obtained in every attempted reproduction in order to establish inherency. He distinguished between products and processes.

"In a process patent case, the application must disclose a functioning process. If the process is ineffectual, the disclosure must be inadequate. Therefore, the process must work every time. In a product patent case, however, the only claim is that when the disclosed process produces a product with certain specified characteristics, that product invariably falls within the Claim. The fact that the process might also produce other non-conforming products is not relevant."<sup>53</sup>

On appeal, the Third Circuit affirmed.

"In considering the application of the invariability rule . . . it is necessary to keep in mind that certain obvious difficulties inhere in imposing a

<sup>49</sup> 107 F.3d at 1571-72, 41 USPQ2d at 1966.

<sup>50</sup> 107 F.3d at 1572, 41 USPQ2d at 1966.

<sup>51</sup> *Standard Oil Co. v. Montedison, S.p.A.*, 494 F. Supp. 370, 206 USPQ 676 (D. Del. 1980), *aff'd*, 664 F.2d 356, 212 USPQ 327 (3d Cir. 1981), *cert. denied*, 456 U.S. 915 (1982).

<sup>52</sup> 494 F. Supp. at 384, 206 USPQ at 693.

<sup>53</sup> 494 F. Supp. at 384, 206 USPQ at 693.

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requirement that repetition experiments must 'invariably' produce the product of the count. Anyone familiar with laboratory experimentation is aware that many variables may affect the success of any particular experiment. . . . Indeed, it is unlikely that evidence of any repetition experiment would be admissible if we were to condition admissibility on the invariable success of all of the other experiments of the same series. Further, the number of experiments to run is in the discretion of the scientist. 'Invariably' successful results will be more likely when fewer experiments are conducted."<sup>54</sup>

In *Hyatt v. Boone* (1998),<sup>55</sup> the Federal Circuit noted that alternate statements in the case law for the written description requirement, to wit, (1) that a written description must "reasonably convey" to an artisan that the inventor possessed the invention, and (2) that the description must "necessarily" set forth the claimed invention, do not establish "divergent standards": "the written description must include all of the limitations of the interference count, or the applicant must show that any absent text is necessarily comprehended in the description provided and would have been so understood at the time the patent application was filed."<sup>56</sup>

<sup>54</sup> *Standard Oil Co. v. Montedison, S.p.A.*, 664 F.2d 356, 372, 212 USPQ 327, 341 (3d Cir. 1981).

See also *Phillips Petroleum Co. v. U.S. Steel Corp.*, 673 F. Supp. 1278, 1291, 6 USPQ2d 1065, 1072 (D. Del. 1987), *aff'd*, 865 F.2d 1247, 9 USPQ2d 1461 (Fed. Cir. 1989) ("The focus . . . is whether the *claimed* subject matter is adequately described."; a claim to "normally solid polypropylene consisting essentially of recurring propylene units, having a substantial crystalline polypropylene content" was adequately supported by the patentee's specification that indisputably described a solid polymer fraction that was in fact such crystalline polypropylene even though that fraction did not have a high molecular weight or intrinsic viscosity such as are necessary for commercial polypropylenes such as those manufactured by the defendants).

Compare *Kennecott Corp. v. Kyocera International Inc.*, 2 USPQ2d 1455, 1457-58 (S.D. Calif. 1986), *rev'd*, 835 F.2d 1419, 5 USPQ 1194 (Fed. Cir. 1987), *cert. denied*, 486 U.S. 1008 (1988) ("It is necessary that the application describe the claim limitations so clearly that persons of ordinary skill in the art will recognize *from the disclosure* that applicants invented the later-claimed subject matter."; "It does not necessarily follow that a patent application which adequately describes a process which inherently will produce a later-claimed product, necessarily adequately describes that product. . . . It must be apparent to one skilled in the art, from the four corners of the application itself, that the claimed product will inherently result from the adequately-described process.").

<sup>55</sup> *Hyatt v. Boone*, 146 F.3d 1348, 47 USPQ2d 1128 (Fed. Cir. 1998), *cert. denied*, 525 U.S. 1141 (1999), discussed at § 13.04[4][a].

See also *Tronzo v. Biomet Inc.*, 156 F.3d 1154, 1159, 47 USPQ2d 1829, 1834 (Fed. Cir. 1998), discussed at § 6.02[9] and § 7.04[2] ("In order for a disclosure to be inherent, . . . the missing descriptive matter must necessarily be present in the parent application's specification such that one skilled in the art would recognize such a disclosure.").

See generally Gholz, "A Critique of Recent Opinions of the Federal Circuit in Patent Interferences," 81 J. Pat. & Trademark Off. Soc'y 241, 248 (1999).

<sup>56</sup> 146 F.3d at 1354-55, 47 USPQ2d at 1132.

In *Hyatt*, the appellant Hyatt argued that the PTO Board "applied an incorrect legal standard in requiring that the specification 'necessarily' describe the entire subject matter of the count."

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Decisions finding sufficient description are legion.<sup>57</sup>

"Hyatt states that a separate body of precedent, typified by *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 19 USPQ2d 1111 (Fed. Cir. 1991), states a different and better standard. In *Vas-Cath* the court stated that the applicant must 'convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention'. . . . Other cases have used the same words in assessing the adequacy of the written description. See, e.g., *Fujikawa v. Watanasin*, 93 F.3d 1559, 1570, 39 USPQ2d 1895, 1904 (Fed. Cir. 1996) ('the disclosure need only reasonably convey to persons skilled in the art that the inventor had possession of the subject matter in question'); *Fiers v. Revel*, 984 F.2d at 1170, 25 USPQ2d at 1606 (same); *In re Kaslow*, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983) (same). Hyatt states that he readily met this requirement, in that . . . his [priority] application reasonably conveyed to persons of skill in this field that he possessed the invention of the count.

"Hyatt argues that 'reasonably conveys to the artisan' is a less rigorous and more reasonable measure of the written description requirement than the 'necessary and only reasonable construction' standard that the Board applied. Precedent has used both phrases, as well as others. See, e.g., *In re Wertheim*, 646 F.2d 527, 538-39, 209 USPQ 554, 565 (CCPA 1981) (the disclosure relied on must 'constitute [] a full, clear, concise and exact description . . . of the invention claimed'). We do not view these various expressions as setting divergent standards for compliance with Section 112. In all cases, the purpose of the description requirement is 'to ensure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by him.' *In re Edwards*, 568 F.2d 1349, 1351-52, 196 USPQ 465, 467 (CCPA 1978).

"The Board did not clearly err in finding that Hyatt did not establish in the [priority] application's written description that he possessed the entire subject matter of the count. This finding comports with the criterion not only of whether the description conveyed to the artisan the specific subject matter of the count, but also of whether the applicant established that this was the necessary construction of that description. The written description must include the limitations of the count with sufficient clarity and specificity that 'persons of ordinary skill in the art will recognize from the disclosure that appellants invented processes including those limitations,' *In re Wertheim*, 541 F.2d 257, 262, 191 USPQ 90, 96 (CCPA 1976)."

146 F.3d at 1354-55, 47 USPQ2d at 1132.

<sup>57</sup> E.g., *In re Daniels*, 144 F.3d 1452, 46 USPQ2d 1788 (Fed. Cir. 1998); *In re Peters*, 723 F.2d 891, 221 USPQ 952 (Fed. Cir. 1983); *In re Edwards*, 568 F.2d 1349, 1352, 196 USPQ 465, 468 (CCPA 1978) (parent application described a reaction, the predominant product of which was the compound claimed in the continuation-in-part application; "on the facts of this case, an adequate description of the aforementioned reactions is, concomitantly, an adequate description of the claimed compound. This should not be construed as meaning that if an application adequately describes a process which, inherently, will produce a compound, then it necessarily adequately describes the compound. Each case must be decided on its own facts."); *Synthetic Industries (Texas), Inc. v. Forta Fibre Inc.*, 590 F. Supp. 1574, 1579, 1581, 224 USPQ 955, 959, 961 (W.D. Pa. 1984) (lowering of minimum range in claim in second application did "not change or affect the basic purpose of the . . . invention"; "the absence of an exact, written description in an application is not, by itself, fatal to the patentability of an invention."); *Fritsch v. Lin*, 21 USPQ2d 1739 (Bd. Pat. App. & Int'f 1991) (claim to recombinant analog of human erythropoietin (EPO), requiring, inter alia, "an average carbohydrate composition which differs from that of naturally occurring human erythropoietin"; the interference party's application, the filing date, the benefit of which an opponent disputed, disclosed a recombinant EPO ("r-EPO") product; HELD: the

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Similarly legion are decisions finding insufficient description.<sup>58</sup>

opponent presented insufficient evidence that recombinant EPO's average carbohydrate composition is the same as natural human EPO); *Flehmig v. Giesa*, 13 USPQ2d 1052 (Bd. Pat. App. & Int'l 1989) ("The law . . . does not require . . . an example to satisfy the written description requirement"); *Ex parte Yamaguchi*, 6 USPQ2d 1805, 1807 (Bd. Pat. App. & Int'l 1987) (the claimed invention, a single-crystal DL-cysteine characterized by an X-ray diffraction spectrum, was adequately described in a prior foreign patent application—even though the prior application did not set forth the spectrum; the prior application disclosed DL-cysteine crystals as the end product of a process; the claimed invention need not be set forth "in *ipsis verbis* to satisfy the description requirement . . . [F]rom a standpoint of patent law, a compound and all of its properties are inseparable. They are one and the same . . . [T]he X-ray diffraction spectrum, like the graphic formulae, the chemical nomenclature, etc., is merely a symbol by which the compound can be identified, classified and compared."); *Driscoll v. Cebalo*, 5 USPQ2d 1477, 1480 (Bd. Pat. Int'l 1982), *aff'd in part, rev'd in part, & remanded*, 731 F.2d 878, 221 USPQ 745 (Fed. Cir. 1984) (as to failure of application to describe literally the chemical compound in question: "the discrepancies, bothersome though they might be, . . . are but obvious typographical errors"); *Ex parte Harvey*, 3 USPQ2d 1626, 1627-28 (Bd. Pat. App. & Int'l 1987) (description requirement met when specification stated that a block dimension "in one particular application" was "5 7/8 inches high, 8 7/8 inches wide and 17 inches long" and that "actual dimensions . . . may vary depending upon the specific application and temperature requirements" and the claim as amended specified a size ratio of "approximately 3:1.5:1;" "The test for determining compliance with the written description requirement is whether the disclosure of the application as originally filed reasonably conveys to the artisan that the inventor had possession of the claimed subject matter, the presence or absence of literal support in the specification for the claim language."); *Ex parte Marsili*, 214 USPQ 904 (PTO Bd. App. 1979) (change in structural formulae of chemical compound that was adequately described in terms of its characteristics in original specification does not violate description requirement).

<sup>58</sup> *Augustine Medical, Inc. v. Gaymar Industries, Inc.*, 181 F.3d 1291, 1303, 50 USPQ2d 1900, 1908 (Fed. Cir. 1999) (claims in a patent ('371), which issued on a continuation-in-part (CIP) application, were not supported by the disclosure of a parent application; the '371 patent's claims were to "a convective warming blanket which covers only a portion of a patient's body."; in the parent application, "the only discussion of care sites relates to those in the head and neck region. Nowhere is there a suggestion, nor is it inherent, that similar blankets may be constructed for the treatment of other care sites."); *Tronzo v. Biomet Inc.*, 156 F.3d 1154, 47 USPQ2d 1829 (Fed. Cir. 1998), discussed at § 6.02[9] and § 7.04[2]; *Hyatt v. Boone*, 146 F.3d 1348, 47 USPQ2d 1128 (Fed. Cir. 1998), *cert. denied*, 525 U.S. 1141 (1999), discussed at § 13.04[4][a]; *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 41 USPQ2d 1961 (Fed. Cir. 1997); *Bigham v. Godfredsen*, 857 F.2d 1415, 1417, 8 USPQ2d 1266, 1268 (Fed. Cir. 1988) (In an interference, if two species of a generic class of compounds are determined to be patentably distinct, a specification disclosure of the generic class cannot be considered a written description of the individual species under 35 USC Section 112; "The generic term 'halogen' comprehends a limited number of species, and ordinarily constitutes a sufficient written description of the common halogen species . . . However, this simple rule does not apply when the count is based on and requires patentable distinction among specific halogens."); *In re Wilder*, 736 F.2d 1516, 222 USPQ 369 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 1209 (1985) (Board of Appeals did not commit clear error in finding no description of mechanism without synchronism when only embodiment in patent was synchronous; title and object sections of specification were not so limited but merely outlined goals and stated a desire to claim as broadly as possible); *In re Kaslow*, 707 F.2d 1366, 217 USPQ 1089 (Fed. Cir. 1983) (finding failure of compliance with description requirement when applicant amended claims to

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